CLAIMS

What Is Claimed Is:

1. A controlled-release pharmaceutical composition, comprising:

1) a core containing an acid-unstable physiologically active substance and a disintegrant; and

2) a release-controlling coating which covers the core, and which contains a water-insoluble polymer, an enteric polymer and a hydrophobic wax.

2. The controlled-release pharmaceutical composition according to claim 1, wherein the release-controlling coating further comprises a plasticizer.

3. The controlled-release pharmaceutical composition according to claim 1 or 2, wherein the core further comprises an alkaline additive.

4. The controlled-release pharmaceutical composition according to any one of claims 1 through 3, further comprising an inert intermediate coating between the core and the release-controlling coating.

5. The controlled-release pharmaceutical composition according to any one of claims 1 through 4, wherein the controlled-release pharmaceutical composition is a pulsed-release pharmaceutical composition.

6. The controlled-release pharmaceutical composition according to any one of claims 1 through 5, wherein the disintegrant is at least one selected from the group consisting of crospovidone, low-substituted hydroxypropyl cellulose,

croscarmellose sodium, and carmellose calcium.

7. The controlled-release pharmaceutical composition according to any one of claims 1 through 6, wherein the water-insoluble polymer is at least one selected from the group consisting of ethyl cellulose, an aminoalkyl methacrylate copolymer RS (Eudragit RS), and shellac.

8. The controlled-release pharmaceutical composition according to any one of claims 1 through 7, wherein the enteric polymer is at least one selected from the group consisting of hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate, a methacrylic acid-methyl methacrylate copolymer (Eudragit L, Eudragit S), and a methacrylic acid-ethyl acrylate copolymer (Eudragit LD).

9. The controlled-release pharmaceutical composition according to any one of claims 1 through 8, wherein the hydrophobic wax is at least one selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carnauba wax, and a hydrogenated oil.

10. The controlled-release pharmaceutical composition according to any one of claims 1 through 9, wherein the water-insoluble polymer is ethyl cellulose, the enteric polymer is a methacrylic acid-methyl methacrylate copolymer (Eudragit L, Eudragit S), and the hydrophobic wax is magnesium stearate or calcium stearate.

11. The controlled-release pharmaceutical composition according to any one of claims 2 through 10, wherein the plasticizer is at least one selected from the

group consisting of triethyl citrate, cetyl alcohol, glycerol fatty acid ester, and propylene glycol.

12. The controlled-release pharmaceutical composition according to any one of claims 1 through 11, wherein a total amount of the water-insoluble polymer and the enteric polymer in the release-controlling coating is 40 to 90 wt%, based on the weight of the release-controlling coating.

13. The controlled-release pharmaceutical composition according to any one of claims 1 through 12, wherein an amount of the hydrophobic wax in the release-controlling coating is 10 to 60 wt%, based on the weight of the release-controlling coating.

14. The controlled-release pharmaceutical composition according to any one of claims 1 through 13, wherein an amount of the water-insoluble polymer in the release-controlling coating is 3.0 to 95 wt%, based on the total amount of the water-insoluble polymer and the enteric polymer in the release-controlling coating.

15. The controlled-release pharmaceutical composition according to any one of claims 2 through 14, wherein an amount of the plasticizer in the release-controlling coating is 0.1 to 20 wt%, based on the weight of the release-controlling coating.

16. The controlled-release pharmaceutical composition according to any one of claims 1 through 15, wherein the acid-unstable physiologically active substance is a benzimidazole-based compound or a physiologically acceptable salt

thereof.

17. The controlled-release pharmaceutical composition according to claim 16, wherein the benzimidazole-based compound or physiologically acceptable salt thereof is rabeprazole, omeprazole, pantoprazole, lansoprazole or esomeprazole, or a physiologically acceptable salt thereof.

18. The controlled-release pharmaceutical composition according to claim 16 or 17, wherein the benzimidazole-based compound or physiologically acceptable salt thereof is rabeprazole sodium.

19. The controlled-release pharmaceutical composition according to any one of claims 3 through 18, wherein the alkaline additive is at least one selected from the group consisting of sodium hydroxide, potassium hydroxide, magnesium oxide, calcium oxide, magnesium hydroxide, and calcium hydroxide.

20. The controlled-release pharmaceutical composition according to any one of claims 1 through 19, wherein the controlled-release pharmaceutical composition is a tablet, a granular preparation, or a fine granular preparation.

21. A capsule preparation, comprising:

the controlled-release pharmaceutical composition according to any one of claims 1 through 20; and

an enteric pharmaceutical composition in which a core containing an acid-unstable physiologically active substance is covered with an enteric coating.

22. A pharmaceutical composition package contained in a packaging container, comprising:

the controlled-release pharmaceutical composition according to any one of claims 1 through 20; and

an enteric pharmaceutical composition in which a core containing an acid-unstable physiologically active substance is covered with an enteric coating,

wherein both of the composition are present in the same packaging container.

23. A pharmaceutical composition package contained in a packaging container, comprising:

the capsule preparation according to claim 21.

24. The pharmaceutical composition package according to claim 22 or 23, wherein the packaging is sachet or blister packaging.

25. A method for producing a controlled-release pharmaceutical composition comprising:

forming a release-controlling coating by spraying a solution containing a mixture of a water-insoluble polymer, an enteric polymer and a hydrophobic wax onto a core containing an acid-unstable physiologically active substance and a disintegrant to form a coating covering the core.

26. The method for producing a controlled-release pharmaceutical composition according to claim 25, wherein the release-controlling coating further comprises a plasticizer.

27. The method for producing a controlled-release pharmaceutical composition according to claim 25 or 26, wherein the core further comprises an alkaline additive.

28. The method for producing a controlled-release pharmaceutical composition according to any one of claims 25 through 27, further comprising forming an inert intermediate coating between the core and the release-controlling coating.

29. The method for producing a controlled-release pharmaceutical composition according to any one of claims 25 through 28, wherein the controlled-release pharmaceutical composition is a pulsed-release pharmaceutical composition.

30. A method of controlling release to reduce variation in a dissolution lag time, comprising: covering a core containing an acid-unstable physiologically active substance and a disintegrant with a release-controlling coating containing a water-insoluble polymer, an enteric polymer and a hydrophobic wax.